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And the Breast is History:
Issues Surrounding FDA Regulation of Silicone Breast Implants

Jodi L. Simme

I.History of Silicone Breast Implants and Their Regulation

Silicone breast implants first appeared on the market over thirty years ago. well before the enactment of The Medical Device Amendments of 1976. Thousands of women in the United States underwent surgery to implant these medical devices into their bodies before the FDA even had any regulatory authority to require a showing of safet or efficacy. Today. an estimated one million women have silicone breast implants. Since the 1976 Amendments, especially in the last ten years. complaints from women with implants have surfaced in alarming numbers. Following a flood of reports detailing adverse effects from the silicone implants. the FDA approved the proposed reclassification of the implants as Class III devices. In July 1991. the FDA required premarket approval of the implants. The FDA has power under Section 515(b) of the Federal Food. Drug and Cosmetic Act to regulate preenactment Class III devices and their postenacrment equivalents by requiring that they are approved for safety and effectiveness.

Be'∼inning in 1988. the FDA requested information and scientific data about implants from the industry and the medical profession, in an attempt to identify risks and benefits of the devices. The response uncovered several serious health concerns related to use of the implants, ranging from chest pain and infection to autoimmune disorders and possible long-term toxic effects of leaking silicone gel. Unfortunately, the data produced left a lot of unanswered questions and uncertainty. In November 1991. an advisory committee heard testimony about risks of implants from medical experts, and about benefits from women who ar∼ued

for the continued availabiltv of implants for both reconstruction and augmentation.[1] The medical reports were largely inconclusive, and the women's testimony apparently had great emotional impact on the panel. The committee recommended leaving the product on the market, despite the fact that safety and efficacy issues left unresolved.

On January 6, 1992. due to continuing complaints and concerns, a moratorium was placed on all silicone breast implants pending further investigation into health risks. Again, the FDA requested information, and received conflicing data and reports. Upon the recommendation of the advisory committee which met again in Febraury 1992, the FDA proceeded to lift the moratorium in April 1992. Severe restrictions, however, were placed on the use of implants. The FDA resolved to allow silicone breast implants for reconstructive purposes, but to prohibit them for cosmetic use.

The FDA has received criticism for its decision regarding silicone breast implants. especially the seemingly arbitrary distinction between the two types of use. This paper will attempt to examine whether the FDA was justified in its decision, and whether a more effective means was available to protect the health of women, while respecting their right to choose.

II.Risks Associated with Silicone Implants

When the FDA gathered information regarding risks of silicone breast implants, it discovered what over ten thousand women already knew. The implants leak and rupture, and often have to be removed because of related medical problems. Women across the country reported chest pain, hardening of the implants, loss of sensation in the breast and nipples, bleeding, infection. fever, skin conditions, dizziness, loss of sleep, memory loss, and hair loss. On the more serious end of the spectrum are reports of soft tissue tumors,

[1]Mark A. Heller. Breast Implants: A Crisis Waiting to Happen, at 247.

breast lumps, tissue disease, auto-immune disease and even death.[2] Nlanv of these complaints have been the impetus for over ten thousand lawsuits involving silicone breast implants filed since 1981.

In addition to first-hand reports, another source of information about the problems with breast implants is found in the evaluation and summary prepared by the FDA.[3] The significant risks identified by the FDA include: 1)fibrous capsular contracture, (2) deflation, (3) infection, (4) interference with early tumor detection. ∼5) human carcinogenicity, (6) human teratogenicity (producting a malformed fetus), (7) adverse immunological effects andor connetive tissue disorders, (8) calcification, and (9) biological effects of silica. Despite the fact that the FDA cited various scientific studies and referred to articles in medical journals, it claimed that further clinical data was needed to make a risk. benefit analysis. Once again, the FDA announced that it was seeking more information.

III.Benefits of Silicone Implants

Even with incomplete medical evidence concerning the adverse effects of silicone implants on a woman's health, the risks of implants can be argued on a more objective level than the benefits. FDA has adopted the position that the benefits of breast implants. whether for reconstruction or augmentation are purely psychological.[4] The effectiveness of breast implants depends on the level of benefit perceived by the woman seeking them, and varies froem patient to patient. Thus, the subjective nature to the benefits associated with the implants are difficult to assess, particularly for the purpose of balancing against risks which include severe physical harm.

As medical devices, silicone breast implants are clearly distinguishable from devices such heart valves or dialysis machines which clearly offer substantial medical benefits. Supporters would be hard-pressed to

[2]See Health Device Alert database, Westlaw.
[3]5SFed.Reg.3436(Januarys, 1993)
[4]Id. at 3439

come up with an argument that a breast implant could save a woman's life.[5] Rather, implants are valued for their cosmetic effect – whether replacing a breast that has been removed or enlarging a breast that is considered too small. This cosmetic effect does seem to benefit many women by improving self-esteem, building selfronfidence, alleviating feelings of inadequacy or unattractiveness. and reducing depression. Not surprisingly, the FDA has suggested the need for scientific documentation of the psychological benefits of implants. If controlled clinical studies could be undertaken, and more objective standards of benefit produced, the FDA and women considering implantation could better analyze the risks and benefits of the devices.

IV.Analysis of the FDA Decision

When the FDA decided to restrict the availability of silicone breast implants, it set the stage for a continuing debate which has left no line of argument unexplored. Morality, free choice, medical knowledge, social constructs and political influence have all played roles in the aftermath of the decision.

A.Why the Distinction?

One of the most troubling aspects of the FDA decision was the seemingly arbitrary distinction drawn between the silicone implants used for reconstruction and those used for augmentation. Implantation is an elective procedure in both situations, and the risks created by the implants exist regardless of the reasons a woman chooses to undergo surgery. This section will explore some possible justifications for treating the two types of use differently.

The FDA rejected an argument that breast reconstruction patients can accept greater long-term risks than augmentation patients.[6] Although the source and reasoning behind this argument were not revealed, it

[5]Although some women claim that but for availability of breast implants, they would have refused to submit to radical mastectomies. My own great-aunt, an exotlc dancer in the days before breast implants had appeared on the market, died of breast cancer because she refused the surgery.

[6]56 Fed. Reg. 14620 (April 10, 1991)

most likely evolved from the idea that women seeking augmentation are generally younger and healthier than women seeking reconstruction. Thus, the risks for augmentation candidates could be viewed as more serious because of the higher likelihood of prolonged exposure to the implants. Women who undergo reconstruction, on the other hand, are generally older and have already gone through the trauma of a major surgery and a major disease. The possibility of developing an auto-immune disorder in the indefinite future might mean little to them. In a sense, they could be seen as having nothing to lose.

The FDA was wise to dismiss this argument. Not only does the assertion over-generalize about the characteristics of implant candidates, but the same reasoning suppports the conclusion that reconstruction patients are *less* able to accept long-term risks of breast implants than augmentation candidates. These women might be more susceptible to long-term risks, especially auto-immune disorders, exactly because they have already submitted to major surgery and have been left weakened by the trauma. Further, it is illogical to argue that a woman who has already been through a life-threatening ordeal will casually accept additional nsks that a woman seeking augmentation would reject.

Despite rejecting a long-term risk differential, and agreeing that the short-term risks are the same for both categories, the FDA maintained thatthe risk/benefit analyses for breast reconstruction and augmentation patients differ.[7] If the health risks are generally the same, it must be the benefits that necessitate the different analyses urged by the FDA.

Since the benefits of breast implants are purely psychological for both categories of patients, any difference must be one of degree. The benefit received by a particular woman will depend on subjective factors such as her perceived need for the implants, her satisfaction with the results of the surgery, and the improvement in her psychological state from before to after the surgery. The FDA believes that the function of the device

[7]56 Fed. Reg. 14620, 14625 (April 10, 1991)

will play a role in the level of benefit.[8]

Surely the benefits of breast implants will vaxy even among women in a given category. For instance, the benefits of augmentation for a woman who is terribly unhappy with her body image and the benefits to an exotic dancer who stands to enlarge her salary by enlarging her breasts are surely different. And yet, each of these women might value the implants even more than a woman seeking reconstructive surgery. Again, the problem is subjectivity. How does one measure benefit to an individual when there is no basis of comparison? Would the FDA agree to a system in which women could have access to breast implants for augmentation as long as they could show a threshhold of benefit at least equal to the benefit received by women in the reconstruction category?

The panel advising the FDA in November 1991 could not distinguish between the needs of women who pursued reconstruction and those who wanted augmentation.[9] Just a few months later, the panel urged the FDA to prohibit breast implants for augmentation, drawing a distinction based on intended use for the devices. The change of heart could have been purely political. Anecdotal testimony from women satisfied with their cosmetic implants was heard at the first meeting of the advisory panel. They were not included in the second meeting. Further, FDA Commissioner David Kessler was reportedly unhappy with the panel's original advice. Could his personal dislike for plastic surgery have been the impetus behind the FDA decision?[10]

There is no discernable difference in risk between reconstruction implants and augmentation implants, and a distinction between the benefits is impossible to determine. Thus, a social or moral judgment could

[8]58 Fed. Reg. 3436, 3441 (January 8, 1993) - The FDA also recognizes the subjective and transient nature of benefits based partially on patient expectations.

[9]Mark A. Heller. Breast Implants: A Crisis Waiting to Happen, at 247.

[10]FDA Insider Peter Barton Hurt tells Harvard Law School class that Kessler views plastic surgery as selr-mutilation, January ∼O, 1995.

be the only true distinction separating the two uses. The American Society of Plastic and Reconstructive Surgeons condemned the FDA for regulating implants on the basis of morality.[11] Regardless of the truth of the accusations. Mr. Kessler would not be the first to have associated breast augmentation with burlesque and to discount the procedure as frivolous.[12] Because many augmentation candidates do work in the sex industry, a certain stigma is associated with breast enlargements, especially those of unusually large size.

However, according to an FDA estimate, eighty percent of breast imolantations were performed for the ourDose of augmentation.[13] Surely these were not all requested by performers. Plenty of ordinary women desire augmentation for reasons other than economic gain. To reduce their desires to something frivolous or immoral trivializes the importance of mental health and deprives some women from feeling good about themselves. The FDA made a mistake by banning silicone breast implants for one purpose but not another. If the devices are truly unsafe and ineffective, they should be banned for all purposes. If not, there should be no limitations, especially those justified only by one man's beliefs ó even if he is the Commissioner.

B.What About Choice ?

Although the FDA would have better served the interests of women by adopting an all or nothing approach, it is not absolutely clear which option should have been pursued ó the all or the nothing. Would women be better off having the opportunity to choose whether breast implants are right for them despite the possible risks, or are women in need of protection against misinformation and external forces? This section will review the arguments for and against a ban on silicone breast implants for any purpose.

[11]At an April 16, 1992 press conference, ASPRS President Norman Cole, M.D. stated, We continue to be disappointed that the government has placed itself in the role of judging the morality of a woman's reasons for choosing breast impl∼∼... The needs of women who seek augmentation of their breasts are poorly understood by those who do not share this desires. Reported in the Gray Sheet, April 20, 1992.

[12]Mark A. Heller. Breast Implants: A Crisis Waiting to Happen, at 247.

[13]56 Fed. Reg. 49098 (September 26, 1991)

The strongest argument against banning silicone breast implants altogether is that it severely restricts the choice of women who desire them for any purpose. Benefits from a cosmetically improved body image are not trivial. Uke it or not, attractive people do gain certain advantages in a society that values superficial beauty. Further, a woman's decision effects no one but herself, so if she makes a personal risk/benefit analysis and is willing to accept the risks associated with implants, it seems that the government has no place telling her no. A complete ban on implants is paternalistic and assumes women cannot sort out the available information and decide for themselves.

A first response to this argument is that paternalism is inherent in regulation. Sometimes the government must substitute its judgment for the protection of people who for some reason are likely to misjudge the harms associated with a certain activity. An example is in the case of illegal drugs.

A second and more significant response is that FDA regulation is needed in the case of breast implants to substitute for a lack of information. The premise of the argument against banning is that women should be able to make an informed choice. If the choice is not informed, it is not really free at all. A number of factors effect the availability of information in the implant context. First, there are still many unanswered questions about the actual health risks involved. Second, societal messages about body shape act as an undue influence on women's choice. Third. implant manufacturers and plastic surgeons can exert subtle, or not-so-subtle pressure on women to choose implantation. All of these factors inhibit the choices avaiable to women and call for government regulation as a counterbalance.

The FDA requires that prospective implant patients be given information about risks associated with the implants. In March 1989. the FDA announced the development of an educational program to assure that women considering surgical implantation of breast prostheses are fully informed of the benefits and

risks associated with the devices before consenting to the surgical procedure.[14] Again in September 1991 the FDA issued a Federal Register notice requiring dissemination of information on risks associated with silicone implants.[15] This time the FDA threatened manufacturers with a charge of misbranding under Section 502(a) of the Food, Drug and Cosmetic Act if the correct information is not included. The FDA asserted that it is crucial for women contemplating implantation to be provided with information on the known, suspected, and potential risks associated with these devices.

Despite this requirement of information to women, the goal envisioned by the FDA has still not been met because of unanswered questions concerning the medical risks. In FDA hearings regarding silicone breast implants, a certain pattern emerges. Health problems related to the implants are reported as potential risks; the FDA requests more information, scientific documentation and clinical studies; the results are incomplete or inconclusive; the process starts all over again. Perhaps the repeated requests for information are a signal as to the root of the information problem. Having been around for only a little over thirty years, and with little or no studies done before marketing, many long term effects of the implants are not yet known, and will not be until women with implants are tracked from the moment of implantation, and evaluated over time for the effects of prolonged contact with the silicone shell. This obviously will take some time ó but surely by now a significant number of wonien could have been subject to studies for long-term effect. Safety concerns were brought to the attention of the medical profession in the early 1980s. Nearly fifteen years later, there are still no clear scientific answers.

The known and potential risks associated with implants are not insignificant. Auto-immune disease and carcinogenicity are serious concerns. Opponents of an FDA ban, however, stress a lack of medical evidence linking these health problems with breast implants. In 1991, the first advisory panel heard testimony from

[14]∼ Fed. Reg. 10729 (March 15, 1989)
[15]56 Fed. Reg. 49089 (September 26, 1991)

scientists and physicians who found no correlation between silicone breast implants and significant health risks.[16] As recently as mid-1994, the New England Jourani of Medicine published a study completed at the Mayo Clinic which showed no link between silicone gel implants and auto-immune disease.[17] Anti-implant arguments, however will point out that the clinical significance of the study's conclusion is in question because of the size of study. Also, a more cynical rebuttal is to analogize the studies to those offered by the tobacco industry to show no correlation between smoking and lung cancer.

Another source of misinformation limiting women's ability to choose is the media. During the height of the breast implant crisis, the media added to the confusion by giving conflicting reports on the safety of implants. Reporters either ignored or didn't understand medical issues well enough to be helpful to women.[18] Reporting health news is not the only role the media has played in the breast implant debacle. Societal messages sent by the media tell women that they should look like models in magazines and actresses on television and in the movies. Since most women are not born looking like super-models. they are pressured to alter their bodies to measure up. The psychological benefits of breast implants are primarily the result of a conditioning of women to believe that they are unattractive if they do not have large breasts (among other things). The FDA reported that [slome studies have shown that women seeking breast enlargement are individuals who feel phsycially indadequate, with doubts concering their femininity and desirability.[19] With feelings like these, which are intensified by constant media images of the right body shape, it is no wonder women don't receive respond to available information, and are willing to disregard significant health risks in order to get implants. While changing societal messages is a job too big for the FDA, it could help combat the resulting effects on women by banning the devices they are encouraged to use.

[16]Mark A. Heller. Breast Implants: A Crisis Waiting to Happen, at 247
[17]Josh Feldstein. Breast Implants: Can a Medical Communications Crisis Be Managed? at 255-256
[18]Id. at 255
[19]58 Fed. Reg. 3436, 3439 (january 8, 1993)

The third factor that interferes with truly free choice by women is propaganda produced by implant manufacturers and plastic surgeons. These two groups obviously have a vested interest in persuading women that they need breast implants. Some of the tactics used are ethically questionable. For instance, in I$83, the American Society of Plastic and Reconstructive Surgeons (ASPRS) invested four million dollars in a public relations campaign encouraging the use of breast implants.[20] The ASPRS compiled brochures which included before and after photographs and represented that cosmetic surgery was safe and inexpensive. The organization also made statements to the effect that flat-chestedness leads to a general lack of well-being and speaking of small breasts, said these deformities are really a disease. This kind of campaign is outrageous. It preys on the insecurities of women and pressures them to undergo painful, risky surgery with false reassurance of safety. The ASPRS also downplays the cosmetic nature of the surgery by conjuring up images of disease. This kind of advertising should be banned regardless of whether the implants themselves are prohibited.

Finally, proponents of choice argue that banning silicone breast implants is unfair and unwise because safe alternatives do not exist. The response to this argument is two-fold. First, there are a number of alternatives currently availabe. Second, more alternatives might be researched and developed if silicone implants were banned for all purposes.

The most viable alternative to silicone gel-filled breast implants are saline-filled implants. They are most similar to the silicone variety in that they are internal prostheses that give the appearance of a real breast. The drawback to saline implants is a cosmetic one. Apparently, they do not feel as genuine as silicone implants. Healthwise, however, the saline implants have an advantage. They are safer than silicone implants because the salt water inside is not harmful to the body if the implant leaks or ruptures. This is an improvement over the silicone gel filling which causes many of the health problems with implants. Saline

[20]Rebecca Weisman. Reforms in Medical Device Deregulations: An Examination of the Silicone Breast Implant Debacle. 23 Golden Gate U. LRev. 973.

implants are currently under FDA review. Potential risks associated with the silicone enclosure are being studied. According to the FDA Talk Paper of December 23, 1994, studies have been proposed through 1998, and information, including preclinical data will be required from the manufacturers of the saline implants.

The FDA has also announced that it is seeking information on other alternatives to implants containing silicone.[21] It has invited scientific authorities to discuss issues of safety and effectiveness, new technology and testing requirements for new devices. Hopefully this attempt will be successful, but some manufacturers may be leery of the long approval process and the potential liability unless silicone implants have been eliminated as competition.

V.Conclusion

The arguments on both sides of the debate are compelling. The breast implant crisis has raised serious issues for women. One one hand, it is difficult to argue against giving women the right to choose, especially when the choice involves their own bodies. Restricting freedom in that realm is politically unpopular these days. On the other hand, women have been harmed by the lack of conclusive health information and by deceptive and coercive messages sent by media, implant manufacturers and plastic surgeons.

For women to benefit from their right to choose, they must have more accurate and complete information. The conflicting studies currently available are insufficient to form the basis of an informed choice. In addition to medical information, women should also be given information about the psychological motivations behind

[21]∼ Fed. Reg. 48330,4833 1

cosmetic surgery. Women should be reminded that they are not freaks or diseased if they have small breasts. Other means of gaining self-esteem and confidence should be explored before the drasitic decision to go under the knife is made. Finally, sources of misleading or deceptive information that results in harm to women should be punished. The Federal Trade Commission does have the authority to monitor advertising which makes claims about specific cosmetic procedures, but nothing short of social reform will combat the misperception that all women must look like models to lead satisfying, fulfilled lives. The role of regulation is important in protecting against societal myths and their resulting harms. Unless women can gain access to the whole story, the FDA should ban breast implants for all purposes in the name of the health and happiness of women.